Application No.: 09/560,597
Filed: April 28, 2000
TC Art Unit: 3626
Confirmation No.: 4637

AMENDMENTS TO THE CLAIMS

1. (Currently Amended) A method of conducting a clinical trial of a test substance over the internet from a primary site, comprising the following steps:

assigning, at the primary site, a unique identifier and a unique log-in password to at least one clinical trial participant located at a remote internet site distinct from the primary site, the unique identifier and the unique log-in password for accessing protected information from the primary site;

providing to the participant, responsive to receipt by the primary site of the unique identifier and the unique log-in password, instructions on: using the test substance; accessing and completing at least one evaluation form from a website maintained at the primary site; and returning electronically said at least one evaluation form to the primary site;

providing, responsive to receipt by the primary site of the unique identifier and the unique log-in password, said at least one evaluation form in electronic format for use by the participant, said at least one evaluation form having a

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question and answer section having at least one question that, when completed by a participant using the test substance, provides information ~~from which a determination can be made of~~regarding one or more effects of the test substance on the participant completing the evaluation form;

completing, by the participant, said at least one evaluation form,

~~wherein~~modifying, while the participant completes said at least one evaluation form in electronic format, at least a portion of the question and answer section included in said at least one evaluation form ~~is modified~~ based at least in part upon one or more responses provided by the participant on at least one ~~of~~ said evaluation form currently being completed by the participant and an evaluation form previously completed by the participant; and

compiling in an investigator accessible form data regarding at least one of said one or more effects of the test substance on the participant from information from at least one received and completed evaluation form returned by the participant to at least one investigator conducting the clinical trial.

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2. (Original) The method of claim 1, further comprising obtaining informed consent from the participant to participate in the clinical trial.

3. (Original) The method of claim 2, wherein obtaining the participant's informed consent comprises sending a blank consent form from the primary site to the remote site, and receiving at the primary site from the remote site, a completed consent form from the participant to participate in the clinical trial.

4. (Original) The method of claim 2, wherein obtaining the participant's informed consent comprises:

causing a consent form to appear at the remote site, said consent form having information about the clinical trial, a portion allowing consent to be given to participate in the clinical trial, and a portion allowing consent to be given to release of the participant's medical information to at least one investigator conducting the clinical trial, and

providing for authentication of the consent form.

5. (Original) The method of claim 4, wherein a computer server at the primary site causes the consent form to appear at the

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remote site computer in response to the primary site receiving from the remote-site, either a request for the consent form or a completed screening questionnaire,

said questionnaire having portions for receiving information for use in making a determination of whether an individual upon whose behalf the questionnaire is answered, is eligible to be a participant in the clinical trial.

6. (Original) The method of claim 2, wherein obtaining the participant's informed consent comprises sending a hardcopy consent form to the participant for completion and return to at least one investigator conducting the clinical trial,

said consent form having information about the clinical trial, a portion allowing consent to be given to participate in the clinical trial, and a portion allowing consent to be given to release of the candidate's medical information to at least one investigator conducting the clinical trial.

7. (Original) The method of claim 1, further comprising screening potential candidates over the internet for eligibility to participate in the clinical trial, the screening comprising:

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- maintaining, at the primary site, a website that is accessible from remote sites via the internet and that provides information about the clinical trial and minimum eligibility criteria for participants in the clinical trial;

- causing a screening questionnaire to appear over the internet at a remote site, after receipt, at the primary site, of a request from the remote site to display the screening questionnaire, wherein the questionnaire has portions for receiving a candidate's information that enables a determination of whether a candidate is eligible to be a participant in the clinical trial;

- receiving the completed questionnaire at the primary site via the internet; and

- reviewing the received questionnaire and making a determination of whether the candidate is eligible to be a participant in the clinical trial according to a set of predetermined criteria.

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8. (Currently Amended) A method of conducting a clinical trial of a test substance over the internet, comprising the following steps:

- maintaining, at a primary site, a website that is accessible from remote sites via the internet and that provides information about the clinical trial and minimum eligibility criteria for participants in the clinical trial;

- causing a screening questionnaire to appear over the internet at a remote site, after receipt, at the primary site from the remote site, of a request to display the questionnaire, wherein the questionnaire has portions for receiving information that enables a determination of whether a candidate, upon whose behalf the questionnaire is completed, is eligible to be a participant in the clinical trial;

- obtaining the candidate's informed consent to participate in the clinical trial;

- receiving the candidate's completed questionnaire at the primary site via the internet;

- reviewing the received questionnaire and making a determination of whether the candidate is eligible to be a participant in the clinical trial according to a set of predetermined criteria;

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- after receipt of the candidate's informed consent by at least one investigator, causing information transfer between the primary site and the remote site for the purpose of confirming the existence, identity, and eligibility of the candidate to participate;

- assigning, at the primary site, a unique identifier and a unique log-in password to at least one clinical trial participant, the unique identifier and the unique log-in password for accessing protected information from the primary site;

- providing, responsive to receipt by the primary site of the unique identifier and the unique log-in password, to the participant, instructions on: using the test substance; accessing and completing at least one evaluation form from a website maintained at the primary site; and returning electronically said at least one evaluation form to the primary site;

- providing, responsive to receipt by the primary site of the unique identifier and the unique log-in password, said at least one evaluation form in electronic format for use by the participant, said at least one evaluation form having a question and answer section including at least one question which when completed provides information regarding ~~from which a~~

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~~determination can be made of~~ one or more effects of the test substance on the participant completing the evaluation form; and

- completing, by the participant, said at least one evaluation form,

- ~~wherein,~~ modifying, while the participant completes said at least one evaluation form in electronic format, at least a portion of the question and answer section included in said at least one evaluation form ~~is modified~~ based at least in part upon one or more responses provided by the participant on at least one ~~of~~ said evaluation form currently being completed by the participant and an evaluation form previously completed by the participant; and

- compiling data in an investigator accessible form regarding at least one of said one or more effects of the test substance on the participant from information from at least one received and completed evaluation form returned by the participant to at least one investigator conducting the clinical trial.

9. (Original) The method of claim 7 or 8, further comprising causing information transfer between the primary site and remote site for the purpose of confirming the existence, identity, and eligibility of the participant.

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10. (Original) The method of claim 7 or 8, wherein the confirming is accomplished by performing at least one step selected from the group consisting of: interviewing the participant by telephone or in person; reviewing at least one medical record of the participant; interviewing a health care professional who has provided health care to the participant; and reviewing at least one communication from the health care professional to the at least one investigator regarding the health status of the participant.

11. (Original) The method of claim 7 or 8, wherein the eligibility of the participant to participate in the clinical trial is determined by comparing the participant's answers to the questionnaire with a reference standard comprising conventionally accepted indications of a medical condition for which the test substance's effectiveness in treating is being tested.

12. (Original) The method of claim 1, 2, 7 or 8, further comprising, prior to compiling data regarding the at least one effect, causing delivery, under authority of the investigator, of the test substance to the participant.

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13. (previously presented) The method of claim 1, 2, 7, or 8, further comprising collecting and storing at a secure site accessible by the at least one investigator and by the participant, information from at least one member of the group consisting of: at least one evaluation form completed and returned by the participant to the at least one investigator; and a screening questionnaire completed and returned by the participant to the at least one investigator.

14. (Original) The method of claim 13, wherein the secure site is the primary site.

15. (canceled)

16. (Original) The method of claim 1, 2, 7, or 8, further comprising monitoring at least one effect of the test substance on the participant by reviewing a plurality of evaluation forms each completed and returned by the participant to at least one investigator, wherein each of the multiple evaluation forms is provided electronically to the participant at predetermined

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different times after the participant has commenced using the test substance.

17. (Original) The method of claim 16, repeated with multiple participants in the clinical trial.

18. (Original) The method of claim 1, 2, 7, or 8, repeated with multiple participants, and further comprising: assigning to each participant, a unique identifier and a unique log-in password for accessing protected information stored at the primary site; and collecting and analyzing data generated by the multiple participants each completing and returning the at least one evaluation form to the at least one investigator.

19. (canceled)

20. (Original) The method of claim 1, 2, 7, or 8, further comprising providing encryption for information transmitted between the primary site and the remote site via the internet.

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21. (Original) The method of claim 16, further comprising providing encryption for information transmitted between the primary site and the remote site via the internet.

22. (Original) The method of claim 18, further comprising providing encryption for information transmitted between the primary site and the remote site via the internet.

23. (Original) The method of claim 1, 2, 7, or 8, wherein the determination of the at least one effect comprises comparing answers from at least one evaluation form completed by the participant after having used the test substance, with answers from at least one evaluation form completed by the participant prior to using the test substance.

24. (Original) The method of claim 17, further determining, from the data compiled from received and completed evaluation forms from multiple participants, whether the test substance has clinical efficacy in treating a predetermined medical condition.

25. (Original) The method of claim 18, further determining, from the data compiled from received and completed evaluation forms

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from multiple participants, whether the test substance has clinical efficacy in treating a predetermined medical condition.

26. (Original) The method of claim 24, wherein determining the test substance's clinical efficacy comprises comparing the compiled data from participants using the test substance with data compiled from information from received and completed evaluation forms returned to at least one investigator by participants using a placebo.

27. (Original) The method of claim 25, wherein determining the test substance's clinical efficacy comprises comparing the compiled data from participants using the test substance with data compiled from information from received and completed evaluation forms returned to at least one investigator by participants using a placebo.

28. (Original) A computer-readable medium carrying a computer program that is operable in the method of claim 1, 3, 4, 5, 7, or 8.

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29. (Currently Amended) A system for conducting a clinical trial of a test substance over the internet from a primary site, comprising at least one computer at the primary site that comprises:

program code for assigning, at the primary site, a unique identifier and a unique log-in password to at least one clinical trial participant located at a remote internet site distinct from the primary site, the unique identifier and the unique log-in password for accessing protected information from the primary site;

program code for providing, via the internet, responsive to receipt by the primary site of the unique identifier and the unique log-in password, to at least one clinical trial participant located at a remote site distinct from the primary site, instructions on: using the test substance; accessing and completing at least one evaluation form from a website maintained at the primary site; and returning electronically said at least one evaluation form to the primary site;

program code for providing, responsive to receipt by the primary site of the unique identifier and the unique log-in password, said at least one evaluation form in electronic format for use by the participant at the remote site, said at least one

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evaluation form having a question and answer section including at least one question that, when completed by a participant using the test substance, provides information ~~from which a determination can be made of~~regarding one or more effects of the test substance on the participant completing the evaluation form; and

program code for modifying, while the participant completes said at least one evaluation form in electronic format, at least a portion of the question and answer section included in said at least one evaluation form based at least in part upon one or more responses provided by the participant on at least one of said evaluation form currently being completed by the participant and an evaluation form previously completed by the participant; and

program code for compiling into a central database at the primary site, investigator accessible data regarding at least one of said one or more effects of the test substance on the participant from information from at least one received and completed evaluation form returned by the participant to at least one investigator conducting the clinical trial.

30. (Original) The system of claim 29, further comprising program code for causing a consent form to appear at the remote site, said consent form having information about the clinical trial, a

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portion allowing consent to be given to participate in the clinical trial, and a portion allowing consent to be given to release of the participant's medical information to at least one investigator conducting the clinical trial.

31. (Original) The system of claim 30, further comprising means for receiving and electronically authenticating a consent form completed and returned via the internet by the clinical trial participant.

32. (Original) The system of claim 29, further comprising means for screening potential candidates over the internet for eligibility to participate in the clinical trial, including:

- means for maintaining, at the primary site, a website that is accessible from remote sites via the internet and that provides information about the clinical trial and minimum eligibility criteria for participants in the clinical trial;

- means for causing a screening questionnaire to appear over the internet at a remote site, after receipt, at the primary site, of a request from the remote site to display the screening questionnaire, wherein the questionnaire has portions for receiving a candidate's information that enables a determination

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of whether a candidate is eligible to be a participant in the clinical trial; and

- means for receiving the completed questionnaire at the primary site via the internet.

33. (Original) The system of claim 32, further comprising means for reviewing the received questionnaire and making a determination of whether the candidate is eligible to be a participant in the clinical trial according to a set of predetermined criteria.

34. (Original) The system of claim 33, wherein the reviewing and determining means provides for comparing the participant's answers to the questionnaire with a reference standard comprising conventionally accepted indications of a medical condition for which the test substance's effectiveness in treating is being tested.

35. (Original) The system of claim 33, further comprising means for informing the candidate, via the internet, of the candidate's eligibility to participate in the clinical trial.

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36. (Original) The system of claim 32, further comprising means for causing information transfer between the primary site and the remote site for the purpose of confirming the existence, identity, and eligibility of the candidate to participate.

37. (currently amended) The system of claim 29, 31, 32, 35, or 36, further comprising a means for encrypting information transferred between the primary site and the remote site.

38. (currently amended) The system of claim 29, 30, 31, 32, 33, 34, 35, or 36, further comprising means for collecting and storing at a secure site accessible by the at least one investigator and by the participant, information from at least one member of the group consisting of: at least one evaluation form completed and returned by the participant to the at least one investigator; and a screening questionnaire completed and returned by the participant to the at least one investigator.

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